DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 18, 2015

Research Instruments Ltd.
David Landsdowne
Technical Director
Bickland Water Industrial Park
Falmouth, Cornwall
TR11 4TA
United Kingdom

Re: K141434
Trade/Device Name: Saturn 5 Laser System
Regulation Number: 21 CFR 884.6200
Regulation Name: Assisted reproduction laser system
Regulatory Class: II
Product Code: MRX
Dated: January 14, 2015
Received: January 20, 2015

Dear David Landsdowne,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
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and Urological Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141434

Device Name
Saturn 5 Laser System

Indications for Use *(Describe)*
For use in assisted reproduction procedures to ablate or thin the zona pellucida of an oocyte or embryo to facilitate assisted hatching or recovery of cells for pre-implantation genetic diagnosis (blastomeres). The device can also be used on blastocyst stage embryos for biopsy of trophectoderm cells for pre-implantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter

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Date prepared :	Thursday, 18 December 2014

Device

Trade Name:	Saturn 5 Laser Systems, Model - Saturn 5 Active Laser System and Saturn 5 Laser System
Device Name:	Assisted Reproduction Laser System
Classification Name:	Laser, Assisted Reproduction (21CFR 884.6200)
Regulatory Class:	II
Product Code:	MRX

Predicate Device

Saturn 3 Laser Systems, K083208 and K060764
This predicate has not been subject to a design related recall.

Description of the device

The Saturn 5 is the latest generation of ART laser systems manufactured by Research Instruments Limited. It is offered in two versions, the fixed and the active models and is designed to enable laser assisted hatching (LAH), laser assisted biopsy (LAB) and related procedures in assisted reproduction clinics.

The system has been designed to be fitted to most commercially available inverted microscopes e.g. Olympus, Nikon and is also used with a PC and camera to provide an optical system and means of firing the laser. A foot pedal for firing the laser is available as an optional extra. The user/customer is requested to confirm their microscope set-up etc, at the point of ordering.

The Saturn system comprises hardware, software and firmware. Hardware components include a control unit, armoured fibre optic patch lead, special 40x objective, a mirror module, motor module (active models only), IR filter and foot pedal (optional). This Saturn 5 system delivers two lasers; the main ablation laser and the pilot laser. Both laser beams are launched from the end of a fibre optic and collimated by an achromatic collimator. Saturn 5, RI Viewer software controls the movement of the laser, fires the laser and allows the user to take measurements and generate and store images.

Saturn 5 differs to the Saturn 3 - Biopsy mode is available with the active model allowing the user to ablate a series of holes along a set, pre-determined path/line. When ‘Biopsy Mode’ has been

activated, the user selects the position of the first and last hole to be drilled by clicking on the screen. A straight line is then clearly defined between these two points which may or may not, depending on user preference, be manipulated (curved) by dragging the center of the line with the mouse pointer. The software determines how many holes are drilled along this line and controls/restricts laser firing parameters e.g. pulse length, to minimize localized heating of the embryo during these procedures.

Indications for Use

For use in assisted reproduction procedures to ablate or thin the zona pellucida of an embryo to facilitate assisted hatching or recovery of cells for pre-implantation genetic diagnosis (blastomeres). The device can also be used on blastocyst stage embryos for biopsy of trophectoderm cells for pre-implantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.

The indications for use statement for the Saturn 5 system is not identical to the predicate device; however the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same assisted hatching intended use.

Comparison of Technological Characteristics with the Predicate Device

The Saturn 5 and Saturn 3 laser systems operate on the same technological principle ie are used to ablate a user defined section zona pellucida of an embryo. Both devices use a pilot laser to align the main laser and each are available as fixed or moveable lasers. At a high level, other similarities are summarised below:

Saturn 3 models	Saturn 5 models
Laser interaction with target	Same
Laser wavelength	Same
Laser power	Same
Laser pulse duration	Same
Laser classification	Same
Laser preset pulse durations	Same
Laser beam target alignment	Same
Objective magnification	Same
Objective focal length	Same
Computer generated target	Same
Exclusion zone	Same
Image capture and video recording	Same
Measurement functions	Same

The following technological differences exist between the subject and predicate devices:

Saturn 3 models	Saturn 5 models
Indications for use	Same but includes blastomere and trophectoderm biopsy
Software	Same but includes Biopsy mode (active model only)

The new intended use (blastomere and trophectoderm) biopsy is achieved using the same technique as the currently cleared use assisted hatching.

Assisted hatching involves the ablation of the ZP at day 3 to promote ‘hatching’ of the embryo once it has been re-implanted. Biopsy procedures require the same treatment ie ablation of the ZP at day 3 but to be able to introduce a biopsy needle to the embryo or to promote the herniation of the TE cells, which can be subsequently be biopsied on day 5/6.

The same size hole would be created for both LAH and for LAB, requiring the same laser pulse length – same location on embryo.

For TE biopsy the laser is also used to dissociate the TE cells from the remaining embryo. By firing several single pulses, whilst holding embryo and extended TE cells under pressure. The laser is used in exactly the same way using the same pre-sets as used for LAH and LAB - to weaken the connections between TE cells. Because the laser is employed using the same settings during LAB procedures as LAH procedures, the embryo is not exposed to any new risks with regard to safety and effectiveness.

Biopsy-mode is a new feature for Saturn 5 and is available with the active model only. It was designed as a time saving feature, allowing the user to ablate a series of holes in succession, along a set, pre-determined path. This mode has no behavioural differences to the single shot in that it executes the same fire command as the single shot mode, but delivers them as a series of shots. Because the same calculations and inhibit time applies as for single shot mode heat is allowed to dissipate within the same time period when using Biopsy mode. There is no limit to the length of the ablation area and this length has no effect on the amount of heat generated, so we can conclude Biopsy Mode performs and is as safe as single shot mode.

Summary of Performance Testing
The following performance data was provided in support of the substantial equivalence determination.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing have been conducted on the Saturn 5 Active Laser System. The system complies with IEC 60601-1:2005 3rd edition safety standards and EN 60601-1-2:2007 for EMC. These standards exceed those met by the predicate ie they are medical device as opposed to general laboratory equipment standards of electrical safety and EMC.

Software Verification and Validation Testing
Software verification and validation testing have been conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of premarket Submissions for software Contained in medical devices." The software for this device was considered as a "moderate" level of concern. This matches evidence provided in the predicate submission.

Laser Testing
Both pilot and main lasers are classified as Class I in accordance with IEC60825:2008 and US 21CFR 1040.10. The Saturn 5 laser system uses the same lasers as the Saturn 3 predicate device.

Clinical Use
The Saturn 5 laser system has been used extensively in the European market since May 2012 with no reported incidents with regard to safety or performance when used as intended, including biopsy use.

Conclusion
This non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrate that the Saturn 5 laser systems should perform as intended in the specified use conditions.